JUL 3 2002

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K013768

Submitter's Identification:

Theratech, Inc.
1109 Myatt Blvd.
Madison, TN 37115
FDA Registration: To be applied for
Phone: 615-865-4000
Fax: 800-485-2626

Date Summary Prepared: November 6, 2001

Name of the Device:

a. **Trade Name:** Ttech NMES

b. **Common Name or Classification Name of Device:**
Powered Muscle Stimulator/Neuromuscular Stimulation (NMES) System

The Physical Medicine Device Panel (DGRD) has classified this device as Class II, 21 CFR Part 890.5850, Product Code 89 IPF.

Predicate Device Information:

NMES:

K951951, EMPI Focus Powered Muscle Stimulator (NMES), EMPI, Inc., 5255 East River Road, Fridley, MN 55421; K003596, RESTIM, Smith and Nephew, Inc. N104 W13400 Donges Bay Rd., Germantown, WI 53022.

Electrode Leads:

K002874, Well-TENS (various model of TENS), Well-Life Healthcare, Inc., Ltd., Taichaung, Taiwan. (the leads are the same for the NMES as for the TENS)

Electrodes:

Wandy Rubber Industrial Co., Ltd. Self-Adhesive Neurostimulation Electrodes, K002219

Device Description: The Ttech NMES is a dual channel NMES device that produces a mild electrical current that is transmitted via leads to electrodes placed on the skin in areas predetermined by the clinician. The device, a set of electrodes with their lead wires, a battery (9 volt), carrying case, and instructions for use make up the Ttech NMES system.

Intended Use:

As an NMES device, the Ttech NMES is indicated for the following conditions:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
- Maintaining or increasing range of motion

Comparison to Predicate Devices:

See attached comparison chart

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:

In addition to performance testing for comparison purposes, the following testing was also completed:

Patient Lead Safety Testing (21 CFR 898)
Test for open /short circuit performance
Temperature endurance test
Incorrect battery installation test
Vibration Test
Mechanical Shock Test
Humidity endurance test
Water immersion endurance test

Discussion of Clinical Tests Performed:

Bench testing raised no additional patient safety or performance issues so clinical testing was not indicated

Conclusions:

The Ttech NMES has the same intended use and technological characteristics as the predicates. No new questions of safety or effectivness have been raised, therefore the Ttech NMES is substantially equivilent to the predicates.

Manufactures	Empi	Smith & Nephew	Theratech
Model Number	Empi FOCUS	RESTIM	Ttech NMES
510(k) Number	K951951	K003596	To be assigned
Equipment Classification	Hand held. Internally Powered	Hand held. Internally powered	Hand held. Internally powered
Output Modality	programmable pulse on/off times and biphasic.	Fixed, Single.	Fixed. Single
Power source	Primary cell, 9V PP3 battery	rechargeable NiMN 8.4V PP3 battery	9 Volt Battery
Recharge Regime	Replace battery.	In situ.	Replace battery
Patient connection	Type BF. Isolated.	Type BF. Isolated. No patient connection is possible during recharge.	Type BF. Isolated
Current pulse regulation	Good.	Good	Good
Maximum output current	60mA	90mA	93mA
Load range	8ohm to 10Kohm	8ohm to open circuit	8ohm to open ciruit
Maximum ouput voltage	+120V	+55V	+100V
Maximum phase charge	3.12 uC.	2.73 uC.	21uC
Peak current density*	$7.92mA/cm^2$	$12.45\ mA/cm^2$	$0.125MAKm^2$
Maximum Power Density**	$4.09X10^{-5}W/cm^2$	$4.29X10^{-6}W/cm^2$	$.0058W/cm^2$
Pulse shape	Symmetric or asymmetric biphasic.	Asymmetric Biphasic	Asymmetrical Biphasic
Pulse pattern	Simple. Programmable repetition rate.	Complex. One second repetition rate	Complex
User set-up method	Multiple rotary dials.	Two switches for intensity increase/decrease	Multiple Rotary Dials
User display	None.	2 digit LCD plus LED	none
Low battery detect	Partial	Yes	Partial
Connection error indication	None.	Yes (open cct)	None
Treatement time	Selectable between 15 mins or continuous.	1 hour fixed	15min - 30min or Continuous
Pulse width	Nominal 260 usec. User adjustable	Nominal 250usec. Can be set between 50 and 350usec by the user.	250usec (fixed)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Theratech, Inc.
C/o Ms. Susan Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

JUL 3 2002

Re: K013768
Trade/Device Name: Ttech NMES
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: April 5, 2002
Received: April 9, 2002

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k)

premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K013768

Device Name: Theratech, Inc. Ttech NMES

Indications For Use:

As an NMES device, the Ttech NMES is indicated for the following conditions:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
6. Maintaining or increasing range of motion

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013768

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)